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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/325,278	10/26/94	BJORCK	L 216764

KARL R. HERMANS  
SEED AND BERRY  
701 FIFTH AVENUE  
SEATTLE WA 98104-7092

HM22/0406

EXAMINER

MINNIFIELD, N

ART UNIT	PAPER NUMBER
1645	23

DATE MAILED: 04/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
08/325,278

Applicant(s)  
BJORCK ET AL

Examiner  
N. M. Minnifield

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Jan 6, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 14-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 14-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 21

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

1. The request filed on January 6, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/325278 is acceptable and a CPA has been established. An action on the CPA follows.
2. Applicants' amendment filed January 6, 1999 is acknowledged and has been entered. Claims 1, 3-5 and 11-13 have been canceled. New claims 14-20 have been added. Claims 14-20 are now pending in the present application. All rejections have been withdrawn, in view of Applicants' amendment, with the exception of those discussed below.
3. Applicants' amendment was received and entered as Paper No. 16. However, the amendment to page 5, line 3 was not entered since it is not clear where the phrase "SUMMARY OF THE INVENTION" is to be entered. Additionally, the amendment to page 5, line 26 and page 9, lines 15 and 16 was not entered since the phrase as set forth in applicants amendment were not present on the lines indicated by applicants. Furthermore, the amendment requesting moving the section to page 5, line 21 was not entered as requested. The Examiner requests applicants provide a substitute specification incorporating the amendments as set forth above.

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4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14 and 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 for the reason set forth in the last Office Action.

Applicants argue the rejection should be withdrawn in view that claims 1-14 of U.S. Patent No. 4,876,194 does not teach the sequence. Applicants' arguments are not sufficient to obviate the rejection. It is reasonable to conclude protein L as set forth in the issued patent is the same, or in the alternative an obvious or analogous variant of protein consisting of SEQ ID No. 1

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as recited in the instant application since they have the same properties (useful as kit, useful as pharmaceutical composition, bind light chains of immunoglobulins, and from *P. magnus* strain 312). Mere discovery that claimed composition possesses property not disclosed for prior art does not *alone* defeat prima facie case of obviousness and it is *not* necessary in order to establish prima facie case, to show both structural similarity between claimed and prior art compound *and* suggestion in, or expectation from, prior art that claimed compound will have same or similar utility as one newly discovered by applicant. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990). For the reasons set forth above and in the last Office Action said rejection is maintained.

Claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 in view of Guss et al. (WO 87/05361)(Art Cited by Applicants in the IDS) and Kastern et al. (1990) (Infection and Immunity 58(5):1217-22 5/90) (Art Cited by Applicants in the IDS) for the reason set forth in the last Office action.

Applicants' argument is set forth above. For the reasons set forth above and in the last Office Action said rejection is maintained.

5. Claims 14 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Kastern et al. 1992 (J. Biol. Chemistry 267(18):12820-25 1992 (Art Cited by Applicants in the IDS)for the reason set forth in the last Office action. Applicants argue the rejection should be withdrawn when a declaration is prepared stating the work of Kastern et al. Is that of the named inventors.

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Until applicants provide a proper declaration said rejection is maintained for the reasons set forth in the last Office Action. This rejection is maintained for the reasons of record.

6. Claims 14 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 255 497 (Art Cited by Applicants in the IDS).

Applicants argue the rejection should be withdrawn since even though EP 0 255 497 teaches subfragments the rejection should be withdrawn since it does not set forth the sequence of protein L. Applicants argument is not persuasive to overcome the rejection. Mere discovery that claimed composition possesses property not disclosed by prior art does not alone defeat prima facie case of anticipation. Since the claimed invention broadly encompasses subfragments of protein L and both the protein L as recited and set forth by EP 0 255 497 are capable of binding light chains of immunoglobulins the claimed invention is anticipated over the disclosure of EP 0 255 497. For the reasons set forth above and in the last Office Action said rejection is maintained.

In view of applicants arguments the Examiner concedes the protein L consisting of the amino acid sequence as recited in claim 1 and 11-13 (now claims 14 and 18-20) is not anticipated over the disclosure of EP 0 255 497. However, since the claimed invention is not limited to a protein which has the amino acid sequence as recited the rejection of the claimed invention over EP 0 255 497 is maintained.

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7. Claims 14 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,876,194 ('194) (Art Cited by Applicants in the IDS).

Applicants argue the rejection should be withdrawn since U.S. Patent No. 4,876,194 does not teach the sequence of protein L. Applicants are not sufficient to obviate the rejection. '194 does not characterize the protein as having the amino acid sequence as set forth in SEQ ID No.1. Nevertheless, since 1) the claimed invention broadly encompasses subfragments of protein L consisting (e.g. having the) of the amino acid sequence and 2) both the protein L as recited and set forth by '194 are capable of binding light chains of immunoglobulins the claimed invention is anticipated over the disclosure of '194.

Since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

For the reasons set forth above and in the last Office Action said rejection is maintained.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

March 19, 1999

  
NITA MINNIFIELD  
PRIMARY EXAMINER